REMARKS

In the Office Action, Claims 1, 2, 7, 8, and 14 to 20 are pending in the application and Claims 1, 2, 7, 8, and 14 to 20 have been rejected. Claims 1, 7, 14, 17 and 19 have been amended to further define the claimed invention.

In the Office Action, Claims 1, 2, 7, 19 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,535,785 to Werge et al. ("*Werge*"). Applicants respectfully submit this rejection has been overcome.

Werge fails to teach or suggest a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve consists essentially of a piston member, said piston member including a single stem and a mushroom-shaped head having an apex, wherein said apex engages a stopper adapted to restrict a movement of the piston member.

In particular, *Werge* fails to teach or suggest a valve consisting essentially of a piston member. Claims 1, 7, and 19 have been amended to provide, among other elements, a valve arrangement comprising a valve consisting essentially of a piston member. In support of its conclusion that *Werge* anticipates the claims of the present invention, the Patent Office states that "[s]ince the claims also include comprising as the first transition term, the other elements of the prior art are deemed acceptable". See page 3 and 4 of the Office Action. The Patent Office seems to suggest that the use of the transition term "comprising" to define which elements are included in the valve arrangement reverses the effect of a more limiting transition phrase used to define which elements are included in a component of the valve arrangement in the claim, namely the valve. However, Applicants submit that although other elements may be included in the valve arrangement of the claimed invention based on the use of the term "comprising", any valve in the valve arrangement is limited to the features specified in the claim along with those features that do not materially affect the basic and novel characteristic of the claimed invention. See MPEP §2111.03. Accordingly, Applicants respectfully submit that, because *Werge* teaches a valve with additional features that would materially affect the basic and novel characteristic of the claimed invention, *Werge* fails to teach or suggest a valve consisting essentially of a piston member.

In addition, *Werge* fails to teach or suggest a valve consisting essentially of a piston member wherein the piston member includes a mushroom-shaped head having an apex which Claims 1, 7, and 19 have been amended to provide, among other elements, a valve arrangement comprising a valve with a piston member that includes a single stem and a mushroom-shaped head having an apex that engages a stopper adapted to restrict a movement of the piston member. Support for this amendment can be found in the Specification at, for example, paragraph [0035]. In contrast to the claimed invention, the valve described and illustrated in *Werge* is essentially flat and does not comprise any portion which could be regarded as an apex. See Fig. 3. In fact, even if the valve in *Werge* is not completely flat, it is inverted and sunken in, in complete contrast to what could be considered to be an apex. Therefore, *Werge* fails to teach or suggest a piston member which includes a mushroom-shaped head having an apex which engages a stopper adapted to restrict a movement of the piston member.

Moreover, *Werge* fails to disclose a valve having a cracking pressure of approximately 0.10 to about 0.20 bar. In order for this subject matter to be anticipated by the reference, *Werge* must disclose the cracking pressure with "sufficient specificity to constitute an anticipation under the statute". See MPEP §2131.03. The valve in *Werge*, however, is described to be activated "under different pressures". *Werge*, column 1, lines 64-66. Such a broad description by *Werge* could encompass an infinite number of pressures preventing one of ordinary skill in the art to "at once envisage" the specific range of pressures of the claimed invention". See MPEP §2131.02. Therefore, any specificity with respect to cracking pressures of the valve in *Werge* is not only insufficient, but completely absent.

In contrast, the valve of the claimed invention achieves unexpected results within the cracking pressure range of approximately 0.10 to about 0.20 bar. As described in the Specification at, for example, paragraphs [0015] through [0020], a valve according to the claimed invention designed to achieve a cracking pressure of approximately 0.10 to about 0.20 bar is suitable for use, for example, with a rotary peristaltic pump (paragraph [0015]), a flow set for the administration of at least one fluid to a patient (paragraph [0016]), in providing nutrition to a patient (paragraph [0018]), etc.. The Specification goes on to explain in paragraphs [0030] and [0031] as follows:

> Remarkably, it has now been found that the specific cracking pressure of the valve of the invention provides a number of advantages. It is not merely a result of optimization of known apparatus. Indeed, it is believed that the specific cracking pressure could not have been arrived at logically without first making an inventive step by realizing that a cracking pressure could be important specifically in the administration of a fluid to a patient.
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> It has been found that these cracking pressures provide the advantage that, if a pump is disconnected from the valve arrangement, fluid is not able to pass through the outlet valve to a patient (or only a small amount of fluid). Therefore, uncontrolled flow to a patient is prevented. It has also been found that these cracking pressures provide the advantage that they do not alter a pump's operation, as they are sufficiently low to avoid any slippage in a peristaltic mechanism.

Therefore, *Werge* fails to disclose a valve having a cracking pressure of approximately 0.10 to about 0.20 bar with sufficient specificity to constitute anticipation of Claims 1, 2, 7, 19 and 20, and the unexpected results of the claimed range renders the claims unobvious. See MPEP §2131.03.

Accordingly, *Werge* fails to teach or suggest a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve consists essentially of a piston member, said piston member including a single stem and a mushroom-shaped head having an apex, wherein said apex engages a stopper adapted to restrict a movement of the piston member. Therefore, *Werge* fails to anticipate the claimed invention.

In the Office Action, Claims 1, 2, 7, 8, and 14 to 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Werge* and further in view of U.S. Patent No. 5,244,463 to Cordner et al. ("*Cordner*") and U.S. Patent No. 5,009,654 to Minshall et al. ("*Minshall*"). Applicants respectfully submit this rejection has been overcome.

Werge, alone or in combination with *Cordner* and *Minshall*, fails to teach or suggest a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve consists essentially of a piston member, said piston member including a single stem and a mushroom-shaped head having an apex, wherein said apex engages a stopper adapted to restrict a movement of the piston member as in the claimed invention. In addition to Claims 1, 7 and 19,

as discussed above, Claims 14 and 17 have also been amended to provide, among other elements, a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve consists essentially of a piston member, said piston member including a single stem and a mushroom-shaped head having an apex, wherein said apex engages a stopper adapted to restrict a movement of the piston member.

As admitted by the Patent Office, *Werge* fails to disclose a valve arrangement suitable for use with a rotary peristaltic pump and a fluid providing nutrition to a patient as in the claimed invention. To cure these deficiencies, the Patent Office combines *Cordner* and *Minshall* with *Werge* to attempt to arrive at the claimed invention. However, *Cordner* merely discloses the use of flow control valves in rotary peristaltic pumps, and *Minshall* only mentions a peristaltic pump and the use of a programmable infusion pump for precise tailoring of fluid delivery rate parameters in different modes such as total parenteral nutrition. Neither *Cordner* nor *Minshall* teach or suggest a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve consists essentially of a piston member, said piston member including a single stem and a mushroom-shaped head having an apex, wherein said apex engages a stopper adapted to restrict a movement of the piston member. Therefore, *Cordner* and *Minshall* fail to cure the deficiencies of *Werge*.

Accordingly, even if it would have been obvious to combine *Werge* with these references, *Werge*, alone or in combination with *Cordner* and *Minshall*, fails to teach or suggest each element of the claimed invention. For at least these reasons, Applicants respectfully submit that the rejection of Claims 1, 2, 7, 8, and 14 to 20 as being unpatentable over *Werge* in view of *Cordner* and *Minshall* has been overcome and should be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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